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10/643,683

08/18/2003

James Robert Swartz

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10/20/2005

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EXAMINER

VOGEL, NANCY S

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|-------------------------------|--|
| Office Action Summary | Application No. 10/643,683 | Applicant(s) SWARTZ ET AL. | |
| | Examiner Nancy T. Vogel | Art Unit 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-13 and 22-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-13 and 22-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 3-7, 13 and 22-26 are pending in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1 and 3-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained essentially for the reasons made of record in the previous Office action, mailed 4/19/05.

Applicant's arguments filed 7/19/05 have been considered but have not been found convincing.

Applicant has argued that by their amendments to the claim 1, which now recites that the method is for the synthesis of polypeptides or polynucleotides, they have overcome the rejection as it is applied to a method of synthesizing any biological macromolecule. Furthermore, applicants argue that the present invention is pioneering, and that prior to the invention "one of skill in the art did not conceive of oxidative phosphorylation as possible in a cell-free system" and furthermore, one can "freely make minor changes in the reaction conditions so as to mimic the results of the present

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invention" (page 4 of the arguments) . However, as was previously set forth in the Office action, claims 1-7 (now claims 1 and 3-7) are genus claims in terms of a method of synthesizing a macromolecule (now limited to polypeptide or polynucleotide) in vitro using any reaction mix where oxidative phosphorylation is activated by any means. While the specification provides a description of a particular reaction mix prepared from E. coli grown under specific conditions (i.e. grown in glucose containing medium, and the reaction mix comprising a specific concentration range of magnesium, free of polyethylene glycol), which result in activated oxidative phosphorylation, there is no disclosure of any other types of reaction mixes having this property, or guidance regarding the identity of such reaction mixes. Therefore, the specification does not describe the claimed method of in vitro synthesis of polypeptides or polynucleotides using reaction mixes where oxidative phosphorylation is activated in such full, clear, concise and exact terms so as to indicate that Applicant had possession of the method at the time of filing the present application. The complete description of the claimed method would require more than "minor changes" of the disclosed method which utilizes E. coli cell extracts grown under particular conditions. Therefore, it is maintained that the specification has not provided a complete description of the method as claimed.

Applicant's arguments with respect to claims 1-13 and 21 under 35 USC 103(a) as being unpatentable over Kim et al. in view of Baranov et al have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

Claims 13 and 22, and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Baranov et al. (Methods in Enzymology, 217, 123-142, 1993) and Chen et al. (Methods in Enzymology, 101, 674-690) (cited for evidentiary purposes only).

Baranov et al. disclose a method of in vitro synthesis of polypeptides in a reaction mix comprising a biological extract from E. coli grown in glucose containing medium, magnesium at a concentration of from about 5 mM to 20 mM, and substantially free of polyethylene glycol. The reaction mix includes spermidine. See Experiment 5 in Table 1. Note that the E. coli extract is disclosed by Baranov et al. (see page 127, first complete paragraph) as being prepared using a standard method such as that disclosed in Chen et al., Methods in Enzymology, 101, 674-690, in which it is disclosed that the E. coli is grown in medium containing glucose and phosphate (see page 675, lines 7-11). Baranov et al. discloses continuous flow cell free reactions, in which plasmid is added, and transcription (production of mRNA) and translation of the encoded protein result.

Claim Rejections - 35 USC § 103

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baranov et al. (cited above) and Chen et al. (cited above).

Baranov et al. disclose a method of in vitro synthesis of polypeptides in a reaction mix comprising a biological extract from E. coli grown in glucose containing medium, magnesium at a concentration of from about 5 mM to 20 mM, and

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substantially free of polyethylene glycol. The reaction mix includes spermidine. See Experiment 5 in Table 1. Note that the E. coli extract is disclosed by Baranov et al. (see page 127, first complete paragraph) as being prepared using a standard method such as that disclosed in Chen et al., *Methods in Enzymology*, 101, 674-690, in which it is disclosed that the E. coli is grown in medium containing glucose and phosphate (see page 675, lines 7-11). Baranov et al. discloses the above method using continuous flow cell free reactions, in which plasmid is added, and transcription (production of mRNA) and translation of the encoded protein result. Baranov et al. disclose that various known cell free translation and transcription-translation systems can be performed using batch process (see page 123, first and second paragraph). The difference between the reference and the instant claim is that batch process is used. However, Baranov et al. disclose that the batch process of cell-free transcription and/or translation is known in the art. While the reference does not explicitly disclose the use of the batch process for the experiment disclosed in Table 1, experiment 5, the reference discloses that such a method is well known in the art and is an alternate technique to method of using continuous flow cell free transcription and/or translation. IT would have been obvious to one of ordinary skill in the art to have utilized a batch process of cell free transcription and translation, using the conditions disclosed by Baranov et al., since Baranov et al. disclose that such method was well known and standard practice in the art. One would have been motivated to do so by the well known benefits of ease of practice and simplicity.

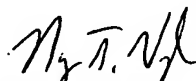
Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


NANCY VOGEL, PH.D.
PATENT EXAMINER